PHARMACEUTICALS **AND MEDICAL** SUPPLIES







and mittant mittant mittant



Pharmaceutical, medical-chemical, and botanical products manufactured for pharmaceutical use **reached USD 531 million¹** in **2018**, according to Bank of Guatemala (Central Bank).

This industry generated a total of 5,892 direct jobs and 60,000 indirect jobs in 2018², which constituted USD 86 million in annual salaries.



Foreign **Trade³**:

Total pharmaceutical and medical-supplies trade (imports and exports) reached USD 1.3 billion in 2019 and an accumulated amount of USD 8.8 billion from 2014 to July 2020. Exports for the whole of last year were USD 401 million, while imports reached USD 978 million. The compound annual growth rate was 2.9% for total trade, stable exports and 4.2% for imports.

According to SIECA's classification, medical supplies can be divided into the following categories: medications, medical equipment, medical supplies, and personal-protection equipment.

Trade	2014	2015	2016	2017	2018	2019		Accumulate Totals 2014 - July 2020	CAGR* 19-14
Exports Imports	396.6 795.9	449.4 894.3	451.5 863.0	387.3 867.8	385.9 942.7	401.8 978.2	307.8 694.1	2,780.2 6,036.1	0.3% 4.2%
Total	1,192.5	1,343.8	1,314.5	1,255.1	1,328.5	I,380.0	1,001.9	8,816.3	3.0%

Guatemala's Foreign Trade (amounts in USD million)

Source: Developed by MINECO with figures from Banco de Guatemala. *CAGR=Compounded Annual Growth Rate.

According to this classification, average trade for 2014 to 2019 was constituted as follows: 63% by medications, 22% by personal-protection equipment, 4% by medical equipment, and 9.7% by medical supplies. In the case of exports, the figures are: 65% for medications, 32% for personal-protection equipment, 5% for medical supplies, and the rest for medical equipment. Imports are composed of 64.9% medications, 11.7% medical supplies, and 17.9% personal-protection equipment. The remaining 5%, approximately, corresponds to medical equipment. In the category of medicines, the production and export of the following therapeutic classes stands out: antihypertensive, Antidiabetic, Ophthalmological (lubricants, antiglaucoma), Dermatological (sun blockers, vitamin C, moisturizers, Anti-inflammatory / analgesics and Antiallergics

I. Reference Exchange Rate: Banguat Q. 7.70 = USD\$ 1.00

^{2.} Source: Banco de Guatemala. Employment Matrix and Production Account.

^{3.} See the Annex for the items used to estimate the data for the sector.

Evolution of Each of the Different Categories

-Exports- (figures in USD million)

Category	2014	2015	2016	2017	2018	2019	2020	Accumulated Total 2014-July 2020
Medications	256.4	304.2	303.8	217.5	209.0	232.1	144.8	I,667.8
Personal - Protection	116.3	7.	123.7	44.	150.5	148.9	140.8	941.4
Medical Supplies	20.5	24.7	20.3	22.6	23.3	18.2	21.0	150.6
Medical Equipment	3.5	3.7	3.8	3.2	3.2	2.7	1.4	21.5
Total	396.7	449.8	451.6	387.3	386.0	401.9	308.0	2,781.3

Source: Developed by MINECO with figures from Banco de Guatemala.



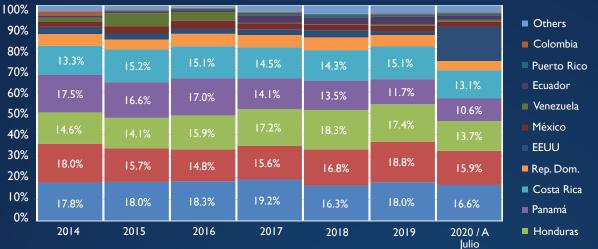
Year-on-Year Growth and CAGR

Category	2015 vs 2014	2016 vs 2015	2017 vs 2016	2018 vs 2017	2019 vs 2018	CAGR 19- 14*
Medications	18.6%	-0.1%	-28.4%	-3.9%	11.1%	-2.0%
Personal - Protection	0.7%	5.6	16.5%	4.4%	-1.1%	-5.1%
Medical Supplies	20.9%	-17.9%	11.1%	3.3%	-21.8%	-2.3%
Medical Equipment	4.7%	2.4	-16.6%	0.0%	-15.4%	-5.4%
Total	13.4%	0.4%	-14.2%	-0.3%	4.1%	0.3%

Source: Developed by MINECO with figures from Banco de Guatemala. *CAGR=Compounded Annual Growth Rate.

The main destination for exports is Central America: Nicaragua accounts for 17.8%; El Salvador, 16.5%; Honduras, 15.9%, Panama, 14.6%, and Costa Rica, 14.4% for the 2014-July 2020 period.

Principals Exportation Destination



Source: Developed by MINECO with figures from Banco de Guatemala.



Following are the 5 main exports⁴:

SECTION	Description	2014	2015	2016	2017	2018	2019
3004909100	Medications for human use	205,289,005	238,599,940	248,473,722	173,416,818	165,142,318	192,878,412
3402200000	Preparations readied for retail sales	63,421,451	62,171,520	71,468,027	80,506,417	87,293,700	80,492,502
3401111900	Soaps	36,197,290	37,321,501	37,634,035	37,718,856	36,620,359	40,428,595
3004501000	Medications for human use containing vitamins	26,104,579	33,654,706	23,187,693	20,042,095	17,778,968	15,405,638
3004201000	Medications for human use containing antibiotics	8,555,654	11,384,472	13,785,325	9,652,142	10,993,839	9,394,414

Source: Developed by MINECO with figures from Banco de Guatemala.



Evolution of the Different Categories – Imports– (figures in USD million)

Category	2014	2015	2016	2017	2018	2019	2020	Accumulated Total 2014-July 2020
Medications	529.4	614.4	570.1	555.8	588.6	602.8	356.0	3,817.1
Personal - Protection	137.1	143.3	149.3	164.9	181.2	183.2	216.3	1,175.2
Medical Supplies	91.9	95.2	102.0	99.9	119.4	121.5	81.1	711.1
Medical Equipmer	nt 43.6	47.2	46.9	53.3	61.7	83.0	47.1	382.9
Total	801.9	900.2	868.3	873.8	950.9	990.5	700.6	6,086.3

Source: Developed by MINECO with figures from Banco de Guatemala.

4. Source: Developed by the author based on data from Banco de Guatemala. See Annex containing the items used.



Year-on-Year Growth and CAGR

Category	2015 vs 2014	2016 vs 2015	2017 vs 2016	2018 vs 2017	2019 vs 2018	CAGR 19- 14*
Medications	16.1%	-7.2%	-2.5%	5.9%	2.4%	2.6%
Personal - Protection	4.6%	4.2%	10.4%	9.9%	1.1%	6.0%
Medical Supplies	3.6%	7.2%	-2.1%	19.5%	1.8%	5.7%
Medical Equipment	8.4%	-0.6%	13.5%	15.9%	34.5%	13.8%
Total	12.3%	-3.5%	0.6%	8.8%	4.2%	4.3%

Source: Developed by MINECO with figures from Banco de Guatemala. *CAGR=Compounded Annual Growth Rate

The trade association for the Pharmaceutical Core Group at the Asociación Guatemalteca de Exportadores –AGEXPORT– has determined that the markets with the greatest potential for medication exports are the following: the Dominican Republic, Ecuador, Bolivia, and Peru. The following tables show the growth of exports to these markets for the 2014-2019 period.

Guatemalan Exports in US\$ under Chapter 30

(Pharmaceuticals)

Categor	ry 2014	2015	2016	2017	2018	2019	2020	Accumulated Total 2014-July 2020
Dominican Republic	11,096,459	11,009,085	11,605,346	9,792,483	9,021,183	11,903,095	8,037,562	72,465,213
Ecuador	3,738,099	2,319,753	3,019,151	6,039,661	3,502,404	5,953,154	1,474,174	26,046,396
Bolivia	26,838	4,120	3,575		44,859	39,106	29,114	147,612
Peru	859,871	394,349	612,123	603,763	73,185	16,427		2,559,718
Total	15,721,267	13,727,307	15,240,195	16,435,907	12,641,631	17,911,782	9,540,850	101,218,939

Source: Developed by MINECO with figures from Banco de Guatemala.



This Year's versus Last Year's Growth

Category	2015 / 2014	2016 / 2015	2017 / 2016	2018 / 2017	2019 / 2018	CAGR 2014-2019
Dominican Republic	-0.8%	5.4%	5.4%	-7.9%	31.9%	1.4%
Ecuador	-37.9%	30.1%	30.1%	-42.0%	70.0%	9.8%
Bolivia	-84.6%	-13.2%	-13.2%		-12.8%	7.8%
Peru	-54.1%	55.2%	55.2%	-87.9%	-77.6%	-54.7%
Total	-12.7%	11.0%	11.0%	-23.1%	41.7%	2.6%

Source: Developed by MINECO with figures from Banco de Guatemala. *CAGR=Compounded Annual Growth Rate.



Trade Agreements in Force

Guatemala is signatory of various trade agreements that allow it preferential access to the following markets:





Industrial Costs



Electric Power

Guatemala has the most competitive electricity rates in the **Central American region.** The cost per kWh is between USD 0.10 for industrial users and USD 0.16 for commercial users. Those users with electricity demand above 100 kW may register as large users and negotiate their electric-power contracts.



Potable Water

In the municipality of Guatemala (if the service is provided by the municipal government):

• The cost of purchasing the rights to water service ranges from: USD 779.22 to USD 6493.50.

• The fee for private water consumption varies, depending on the range of consumption. The endpoints are from I to 20 m3, a fixed rate of USD 2.08 plus USD 0.29 per m3 used, and for 121 m3 and up, a fixed rate of USD 2.08 plus USD 1.45 per m3 used.



Average Monthly Salary⁶

• To manufacture pharmaceutical, medical-chemical, and botanical products for pharmaceutical use 7, **USD 1,219.89**

• To manufacture soaps and detergents, cleaning and polishing preparations, perfumes, and toiletries , **USD 984.35**



Rent

• Warehouse: a monthly rent ranging from **USD 3.50** – **USD 6.00 per square meter** in the Municipality of Guatemala and coalesced municipalities such as Mixco, Amatitlán and Villa Nueva.

• Industrial park: a monthly rent ranging from USD 3.50 – USD 6.00 per square meter in the Municipality of Guatemala and surrounding areas

• Special Public Economic Development Zones: a monthly rent within a range of **USD 6.50 per square meter** in the departments of Escuintla and San Marcos.

5. Rates vary in each municipality. The Municipality of Guatemala is used as reference, according to the Municipality of Guatemala's Municipal Council Agreement No. COM-036-03 and its amendments COM-002-06 and COM017-07. The cost of purchasing the right to potable-water service varies, depending on the type of classification applied, and it is determined by the Municipality of Guatemala on a case-by-case basis.



7. Classification AE046, according to the Nomenclature of Economic Activities for Guatemala, Banguat.

8. Classification AE045, according to the Nomenclature of Economic Activities for Guatemala, Banguat. This category is considered because it includes the production of alcohols and other types of disinfectants that are considered as medical inputs.



Routes and Estimated Logistic Costs

Land Transportation

Place of Origin	Destination	Cost USD (40' Container)
Guatemala City	San Salvador, El Salvador (291 kms)	650
Guatemala City	San Pedro Sula, Honduras (526 kms)	1,010
Guatemala City	Managua, Nicaragua (840 kms)	1,720
Guatemala City	San José, Costa Rica (1,250 kms)	2,500
Guatemala City	Panama City, Panamá (2,135 kms)	4,200
Guatemala City	Ciudad Hidalgo, México (256 kms)	650

Source: Cámara de Transportistas Centroamericanos (Chamber of Central America Carriers – CATRANSCA–)

Marine Transportation

Place of Origin	Destination	Cost USD (40' Container)
Long Beach California	Puerto Quetzal Guatemala	2,521
Shangai, China	Puerto Quetzal Guatemala	428
Rotterdam, Países Bajos	Puerto Santo Tomás de Castilla, Guatemala	3,733
Miami FL, EEUU	Puerto Santo Tomás de Castilla, Guatemala	2,953
Santo, Brasil	Puerto Quetzal Guatemala	7,256
Puerto Buenaventura, Colombia	Puerto Quetzal Guatemala	I,475
Puerto Buenaventura, Colombia	Puerto Santo Tomás de Castilla, Guatemala	1,650
Heroica Veracruz, México	Puerto Quetzal Guatemala	1,914
Manzanillo, Colima, México	Puerto Quetzal Guatemala	548
Place of Origin	Destination	Cost USD USD (40' Standard Dry Container)
Puerto Santo Tomás, Guatemala	Rio Haina, Dominican Republic	2,400-2,800
Puerto Quetzal, Guatemala	Veracruz, México	3,000-3,500
Puerto Quetzal, Guatemala	Caldera, Costa Rica	2,200 – 2,500

Source: AGEXPORT

Air Transportation

Place of Origin	Destination	Cost USD (40' Container)
Guatemala (GUA)	EEUU, Miami (MIA)	0.80 a 1.10
Guatemala (GUA)	EEUU, Los Ángeles (LAX)	I.I0 a I.20
Guatemala (GUA)	Panamá (PTY)	0.80 a 1.30
Guatemala (GUA)	Spain, Madrid (MAD)	I.5 a I.90
Guatemala (GUA)	United Kingdom, Heathrow (LHR)	I.2 a 2.00
Source: ACEXPORT		



Operations Infrastructure

(reference to 2019)

Guatemala has the infrastructure you need for your business operations.



Electric Power ⁹

Installed capacity **3,488 MW** Maximum demand **1,785 MW** Energy matrix: **60% renewable; 40% non-renewable** Average Spot Price (2019) **63.32 USD/MW**



Potable-Water and Sanitation Systems¹⁰

Over 97 million cubic meters of water available per year (7 times greater than the water-risk limits established by international standards).



Telecommunications "

2 million landlines20 million mobile cellular lines7 registered international-port operators



Road Network, Seaports and Airports

- Seaport commercial operations in the Pacific coast (Puerto Quetzal) and the Atlantic coast (Puerto Santo Tomás de Castilla).
- 249 miles of roads connecting the Pacific and Atlantic coasts
- 2 international airports, 9 local airfields, 22 commercial airlines, and 11 air cargo carriers operating.

9. Source: Statistical Reports 2019, Administrador del Mercado Mayorista (Wholesale Market Administrator) 10. Source: SEGEPLAN 2019

11. Source: Statistics Bulletin Superintendency of Telecommunications -SIT-



International airports

I. La Aurora in Guatemala City 2. Mundo Maya en Petén



Ë=8<u>-</u>

Main Road Network

Ports

I. Puerto Quetzal

2. Puerto Santo Tomás de Castilla

3. Puerto Barrios

00

CA-01	Distance 2,462 km	CA-05	Distance 418 km
CA-02	Distance 674 km	CA-06	Distance 170 km
CA-03	Distance 259 km	CA-07	Distance 193 km
CA-04	Distance 384 km	CA-08	Distance 92 km
CA-09	Distance 404 km	CA-13	Distance 795 km
CA-10	Distance 118 km	CA-14	Distance 128 km
CA-II	Distance 384 km		
CA-12	Distance 152 km		

6,525 km

of Central American roads





Local aerodromes

- I. Puerto Barrios
- 2. Quetzaltenango
- 3. Quiché
- 4. Cobán
- 5. Retalhuleu



6. Huehuetenango

8. Poptún

9. Esquipulas

7. Puerto de San José

Land Customs

I. El Ceibo 2. La Mesilla 3. El Carmen

- 4. Tecún Umán II
- 5. Tecún Umán I
- 6. Corinto*

7. Agua Caliente* 8. El Florido*

: 1

- 9. La Ermita
- 10. San Cristóbal
- I I.Valle Nuevo
- 12. Pedro de Alvarado

* Integrated border posts of Guatemala in the Customs Union with Honduras.



Competitive **Advantages**



The pharmaceutical sector has been present in the region (C.A. and the Caribbean) for over 40 years. It generates almost 5,892 direct and 60,000 indirect jobs in commercialization, manufacturing, and logistic operations as well as clinical research services.



There are 42 pharmaceutical companies in Guatemala that comply with the USP and EP quality and specifications and with the Good Manufacturing Practices, according to Report 32 of the World Health Organization –WHO– norms. This is the largest conglomerate of pharmaceutical laboratories in Central America, offering quality products at prices that are competitive at the national and international levels.



Guatemala is the epicenter of pharmaceutical, vitamin and natural-product development, production, and commercialization in Central America. The pharmaceutical industry has established itself as the main exporter and supplier of pharmaceutical products in the region as a result of its competitiveness and leadership.



Availability of skilled labor for research and production, with over 6,000 professionals accredited by the Professional Association of Pharmacists and Chemists.



There are professional technical courses of study at the state university and two private universities, one of which is accredited by HCERES.



There is a business cluster of basic inputs such as packaging, raw materials, analysis laboratories, logistic services and consultancies that are part of the value chain of the Guatemalan pharmaceutical sector.



Competitive financing, energy, telecommunications, and logistic costs.



Direct access to an expanded market of 60 million people in Central America, Mexico and the United States.



Strategic geographic location with access to seaports in the Pacific and Atlantic oceans.



Central American Free Trade Zone (including Panama) and free movement of goods with Honduras (Guatemala-Honduras Customs Union). Largest Central American exporter.



Doing Business Index (2020)

Guatemala is positioned on the top 10 countries with the best ranking in Latin America and the Caribbean in the Doing Business Index 2020.



Opening a business

Guatemala placed first among Latin American and Caribbean countries in regard to improving its competitiveness to open a business.

The average number of steps required to open a business in Guatemala is six, and the estimated time to undertake those steps is 15 days.



Electric Power Procurement

Second place among the countries of the region regarding its rating for energy supply reliability and the transparency of its rates.



Securing Credit

In regard to the strength of legal rights, Guatemala ranked second among the countries of the Central American region, and it is above the indicators for Latin America and the Caribbean



Paying taxes

The country has the lowest rate of taxes and contributions levied as a percentage of earnings in the Central American region.



Cross-Border Trade

The country ranks second among Central America countries for having the lowest export and import costs (border and documentary compliance).



Construction Permit Management

Less number of procedures and competitive costs.

	Regulatory Framework
	Health Code and its set of regulations • Decreto 90-97 - Health Code MOWNLOAD
2	Government Agreement 712-99 and its amendments - Set Of Health-control Regulations For Medications And Similar Products
3	Central American Technical Set of Regulations (RTCA 11.03.42:07) – Pharmaceutical Products For Human Use, Good Manufacturing Practices For The Pharmaceutical Industry.
4	Central American Technical Set of Regulations (RTCA 11.03.59:11) – Pharmaceutical Products. Medications For Human Use. Health Registry Requirements.
5	Central American Technical Set of Regulations (RTCA 11.01.02:04) Pharmaceutical products. Labelling pharmaceutical products for human use.
6	Central American Technical Set of Regulations (RTCA 11.03.47:07) Pharmaceutical products. Medications for human use. Quality verification.
7	Decree 28-2011. Law to Combat Production and Commercialization of Counterfeit Pharmaceutical Products, Adulterated Medications, and Counterfeit Medical and Surgical Devices and Materials.



Fiscal and Non-Fiscal Incentives

Decree 16-2003 – Law on Valued Added Tax

Generic Medicines. Generic and alternative doctors of natural origin constitute a significant economic assistance to Guatemalans, a situation that encourages them to be exempt from Value Added Tax -IVA-.

DOWNLOAD

Law on Foreign Investment (Decree 9-98):

Equal acknowledgement of foreign and local investors. The law does not allow the State to expropriate, directly or indirectly, any investment that has been made.

b download

Law Promoting and Developing Export and Maquila (Outsourcing) Activities (Decree 29-89) – Amended by the Emerging Law for Job Preservation (Decree 19-2016):

- Firms could claim the benefits generated by this law by being classified as export firms or as maquila companies under the temporary admission regime.
- Temporary cessation of payment of customs duties and import taxes.
- Temporary cessation of DAI (customs duties) and VAT payments levied on raw materials, samplers, components, and accessories that are necessary for the productive process.
- b DOWNLOAD

Set of Regulations to Authorize and Implement the Special Public Economic Development Zones (Decree No. 30-2018):

- Income Tax (ISR) exemption for 10 years.
- Temporary cessation of VAT, customs duties, and other charges on imports of raw materials, inputs, materials, machinery, equipment, accessories, etc.
- Exemption of fiscal stamps on documents containing acts or contracts on goods and business in the Special Public Economic Development Zones.

DOWNLOAD



Nucleus of the Pharmaceutical Industry in Guatemala

A core group of 20 pharmaceutical companies (certified by WHO GMP's Regulations) organized and focused on market diversification and on meeting the growing demand for products in Latin America and the Caribbean. To that end, there is a sectoral agenda centered on promoting initiatives and projects that continue to build on its international positioning. The following are some of the strategic projects being promoted.

- **Pharma Innovation & Trends**, which is an innovation forum showing the main product trends at the international level to develop and innovate pharmaceutical products.
- **MANUFEXPORT**, a business conference to establish links among international buyers from Central America, the United States, the Dominican Republic, Peru, Ecuador, and Bolivia, among others.
- **EXPORT FARMA**; business-strengthening programs on BMPs, national health norms and norms to access international markets.
- Initiatives to streamline health registries at the national level and in the Central American region.



